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| EXAMINER | |
|---|---|
| TONGUE, LAKIA J | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/565,347 | SOOTHILL ET AL. | |
| | Examiner | Art Unit | |
| | LAKIA J. TONGUE | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *35-37,40,41,43,46,47 and 76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-37,40,41,46 and 76* is/are rejected.

7)☒ Claim(s) *43 and 47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. Applicant's response filed on September 15, 2009 is acknowledged. Claims 38, 39, 42, 44, 45, 49-53, 55-59, 61, 62 and 65-75 have been canceled. Claim 76 has been added. Claims 35-37, 40, 41, 43, 46, 47 and 76 are currently pending and under examination.

### *Objections Withdrawn*

2. In view of Applicant's amendment, the objection to the disclosure because it contains embedded hyperlinks and/or other form of browser-executable codes, for example pages 2-4 is withdrawn.

3. In view of Applicant's amendment, the objection to claim 46 because it depends on a non-elected claim is withdrawn.

### *Rejections Withdrawn*

4. In view of Applicant's arguments and amendments, the rejection of claims 35-38, 40, 42 and 43 under 35 U.S.C. 102(b) as anticipated by Slopek et al. (Archivum Immunologiae Et Therapiae Experimentals, 1984; 32(3): 317-35) is withdrawn.

5. In view of Applicant's arguments and amendments, the claims 35-43 under 35 U.S.C. 103(a) as being unpatentable over Slopek et al. (Archivum Immunologiae Et

Therapiae Experimentals, 1984; 32(3): 317-35) is withdrawn. The cancellation of claims 38, 39 and 42 renders the rejection of said claims moot.

6. In view of Applicant's amendment, the rejection of claims 35-43, 46, 47 and 67 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (this is a new matter rejection) is withdrawn. The cancellation of claims 38, 39 and 42 renders the rejection of said claim moot.

7. In view of Applicant's amendment and arguments, the rejection of claims 35-43, 46, 47 and 67 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn. The cancellation of claims 38, 39 and 42 renders the rejection of said claim moot.

***Rejections Maintained***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. The rejection of claim 46 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained for the reasons set forth in the previous office action.

Applicant argues that:

1) Copies of the deposit receipts for the cell lines of interest are provided.

Applicant's arguments have been considered but are deemed non-persuasive.

With regard to Point 1, Applicants claims are drawn to a panel of bacteriophages, which include NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179. However, Applicant has only provided a deposit receipt for NCIMB 41181, which has not been claimed. Applicant has not provided proper documentation for the claimed bacteriophages.

As previously presented, claim 46 is drawn to a method of treating a bacterial infection characterized by biofilm formation, wherein said bacterial infection comprises *Pseudomonas aeruginosa*, and wherein said method comprises: a) administering to a human or non-human animal in need thereof one or more bacteriophage preparations comprising one or more bacteriophages, wherein said one or more bacteriophages target and kill said *Pseudomonas aeruginosa* present in the biofilm; and b) sequentially

administering one or more antibiotics active against a bacterial species present in the biofilm, wherein said one or more antibiotics is administered after the one or more bacteriophages has commenced replication in a targeted *Pseudomonas aeruginosa* present in the biofilm, wherein a panel of bacteriophages is employed consisting of NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179.

Because it is not clear that cell lines possessing the properties of **NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179** are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the claims require the use of a suitable deposit for patent purposes a deposit in a public repository is required. Without a publicly available deposit of the above **NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179**, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell line is an unpredictable event.

Applicant's referral to the deposit of **NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179 on page 12** of the specification is an insufficient assurance that all required deposits have been made and all the conditions of 37 CFR 1.801-1.809 have been met. If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by the International Depository Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application. These requirements are necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the

specification to recite the date of the deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring: (a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request; (b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application; (c) the deposits will be maintained in the public repository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and (d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the repository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of biological material not made under the Budapest Treaty must be filed in the application and must contain: 1) The name and address of the depository; 2) The name and address of the depositor; 3) The date of deposit; 4) The identity of the deposit and the accession number given by the depository; 5) The date of the viability test; 6) The procedures used to obtain a sample if test is not done by the depository; and 7) A statement that the deposit is capable of reproduction. As well as a

statement that removes restrictions to provide access to this strain upon granting of a patent has been made, neither in the instant Specification, nor in Applicant's Remarks.

One of the critical conditions of Deposit is defined in 37 CFR 1.808 requires that the deposit of biological material be made under two conditions: (A) access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C. 122, and (B) with one exception, that all restrictions imposed by the depositor on the availability to the public of the deposited biological material be irrevocably removed upon the granting of the patent. Upon making this statement, the rejection under 35 USC 112, first paragraph will be withdrawn. This rejection can be obviated through perfection of the Deposit and amendment of the claims to clearly set forth the Deposited strains.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit. If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the **NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179** described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F.2d.1216, 227 USPQ (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

9. The rejection of claim 46 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating canine ear infections related to *P. aeruginosa* comprising administering to an animal in need thereof a bacteriophage preparation consisting of NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179 (BioVet-Pa) together with one or more antibiotics, does not reasonably provide enablement for to a method of treating a bacterial infection characterized by biofilm formation, wherein said bacterial infection comprises *Pseudomonas aeruginosa*, and wherein said method comprises: a) administering to a human or non-human animal in need thereof one or more bacteriophage preparations comprising one or more bacteriophages, wherein said one or more bacteriophages target and kill said *Pseudomonas aeruginosa* present in the biofilm; and b) sequentially administering one or more antibiotics active against a bacterial species present in the biofilm, wherein said one or more antibiotics is administered after the one or more bacteriophages has commenced replication in a targeted *Pseudomonas aeruginosa* present in the biofilm is maintained for the reasons set forth in the previous office action. Applicant's amendment to claim 47 renders the rejection of said claim moot. The cancellation of claim 67 renders the rejection of said claim moot.

Applicant argues that:

1) The pending claims are directed to a method of treating a bacterial infection.

2) The claims recite the use of bacteriophages that target, kill, and replicate in *Pseudomonas aeruginosa* present in the biofilm.

3) The current claims are directed towards *Pseudomonas aeruginosa* and the Applicant has received confirmation from the FDA and EMEA that the Applicant's data are acceptable to support Phase III clinical trials.

Applicant's arguments have been considered and are deemed non-persuasive.

With regard to Point 1, while the claims have been amended to recite that the bacterial infection comprises *Pseudomonas aeruginosa,* the claims are broadly drawn and encompass a method of treating any bacterial infection that comprises *Pseudomonas aeruginosa*, which is not limited to an infection selected from infection of a skin burn or other skin wound, a lung infection, an ocular infection, a urinary infection or infection associated with a medical device or implant comprising administering any one or more bacteriophage preparations comprising any one or more bacteriophage.

With regard to Point 2, while the claims recite the use of bacteriophages that target, kill, and replicate in *Pseudomonas aeruginosa* present in the biofilm, the claims remain broad and do not specifically claim the bacteriophages that have been shown to demonstrate said function in the specification. The specification is enabled for a method of treating canine ear infection related to *P. aeruginosa* comprising administering to an animal in need thereof a bacteriophage preparation consisting of NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179 (BioVet-Pa) together with one or more antibiotics.

With regard to Point 3, the confirmation and guidelines set forth by the FDA and EMEA have no barring on the prosecution of this application; therefore, Applicant's argument is moot.

As previously presented, *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. Thus, Applicant assumes a certain burden in establishing that inventions involving physiological activity are enabled.

Factors to be considered in determining whether a disclosure would require undue experimentation have been reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CRFC1988). The Wands factors have been considered in the establishment of this scope of enablement rejection. These factors include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

***Nature of the invention:*** The claimed invention is directed to a method of treating a bacterial infection characterized by biofilm formation, wherein said bacterial infection comprises *Pseudomonas aeruginosa*, and wherein said method comprises: a) administering to a human or non-human animal in need thereof one or more bacteriophage preparations comprising one or more bacteriophages, wherein said one or more bacteriophages target and kill said *Pseudomonas aeruginosa* present in the

biofilm; and b) sequentially administering one or more antibiotics active against a bacterial species present in the biofilm, wherein said one or more antibiotics is administered after the one or more bacteriophages has commenced replication in a targeted *Pseudomonas aeruginosa* present in the biofilm.

***Breadth of the claims:*** The claims are broadly drawn and encompass a method of treating any bacterial infection that comprises *Pseudomonas aeruginosa*, which is not limited to an infection selected from infection of a skin burn or other skin wound, a lung infection, an ocular infection, a urinary infection or infection associated with a medical device or implant comprising administering any one or more bacteriophage preparations comprising any one or more bacteriophage.

***Direction or guidance presented in the specification:*** The specification provides enablement for a method of treating canine ear infections related to *P. aeruginosa* which comprises administering to an animal in need thereof a bacteriophage preparation consisting of NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179 (BioVet-Pa) together with one or more antibiotics. However, the specification lacks enablement for a method of treating any bacterial infection comprising *P. aeruginosa*, which comprises administering any one or more bacteriophage preparations comprising any one or more bacteriophage.

The specification is silent with regard to which bacterial infection can be treated when a patient in need thereof is administered any bacteriophage. It is unclear which combined bacteriophage preparation comprising a plurality of bacteriophages will have the capability of infecting the same bacterial species, wherein each member of said plurality of bacteriophages have a different strain specificity, as recited in claim 37 and still retain the ability to treat or prevent any bacterial infection characterized by biofilm formation.

Moreover, the claims are drawn to any bacterial infection, which is not limited to, but can include an infection selected from infection of a skin burn or other skin wound, a lung infection, an ocular infection, a urinary infection or infection associated with a medical device or implant. Lung infections alone are caused by bacteria and viruses as well as fungi. The specification is silent with regard to how the claimed method will

successfully combat, for example a viral or fungi based lung infection.

***Presence or absence of working examples:*** There are no working examples provided to rectify the missing information in the instant specification pertaining to the claimed variant.

***Quantity of experimentation necessary:*** The quantity of experimentation necessary would be undue as the claims encompass a method of treating any bacterial infection comprising administering any one or more bacteriophage preparations comprising any one or more bacteriophage. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to make/use the claimed genus. In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention. Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and working examples provided in the specification and the high degree of unpredictability as evidence by the state of the prior art, attempting the construct and test variants of the claimed invention would constitute undue experimentation.

## *New Grounds of Objection/Rejection Necessitated by Amendment*

### *Claim Objections*

10. Claims 43 and 47 are objected to because of the following informalities: Claims 43 and 47 depend on rejected based claims. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 35-37, 40 and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Sharp et al. (WO 2004/062677 A1, filing date of 1-10-03).

The rejected claims are drawn to a method of treating a bacterial infection characterized by biofilm formation, wherein said bacterial infection comprises *Pseudomonas aeruginosa*, and wherein said method comprises: a) administering to a human or non-human animal in need thereof one or more bacteriophage preparations comprising one or more bacteriophages, wherein said one or more bacteriophages target and kill said *Pseudomonas aeruginosa* present in the biofilm; and b) sequentially administering one or more antibiotics active against a bacterial species present in the biofilm, wherein said one or more antibiotics is administered after the one or more bacteriophages has commenced replication in a targeted *Pseudomonas aeruginosa* present in the biofilm.

Sharp et al. disclose a composition for treating a bacterial biofilm, comprising administering a bacteriophage and may further comprise one or more pharmaceutically acceptable antimicrobial agent which includes an antibiotic (see page 7, lines 1-5).

Sharp et al. disclose that the bacteriophage targets *Pseudomonas aeruginosa* (see page 9, lines 1 and 3). Sharp et al. disclose that the method involves administration of at least one dose of bacteriophage and that the phage may be administered at the same time, prior to, or subsequently to one another (see page 18, lines 20-25). Moreover, Sharp et al. disclose that the phage may be highly specific in the destruction of their targets and that combinations of different phage may be employed (see page 8, lines 1-3). Sharp et al. disclose in one embodiment that the repeated use of phage and antibiotics is employed (see page 19, lines 4-6). The medical treatment of the present invention is suitable for treatment of biofilm infections of the lung (see page 19, lines 11 and 12).

The method steps of the instant claims are identical to the method steps employed in Sharp et al., absent evidence to the contrary, the method steps of Sharp et al., is necessarily capable of treating an ear infection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claim 76 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sharp et al. (WO 2004/062677 A1, filing date of 1-10-03) as applied to claims 35-37, 40 and 41 above.

The rejected claims are drawn to a method of treating a bacterial infection characterized by biofilm formation, wherein said bacterial infection comprises *Pseudomonas aeruginosa*, and wherein said method comprises: a) administering to a human or non-human animal in need thereof one or more bacteriophage preparations comprising one or more bacteriophages, wherein said one or more bacteriophages target and kill said *Pseudomonas aeruginosa* present in the biofilm; and b) sequentially administering one or more antibiotics active against a bacterial species present in the biofilm, wherein said one or more antibiotics is administered after the one or more bacteriophages has commenced replication in a targeted *Pseudomonas aeruginosa* present in the biofilm.

Sharp et al. disclose the limitations as set forth above. Sharp et al. do not specifically disclose that the antibiotic is delayed by at least one day after administration of said one or more bacteriophage preparation.

It would have been prima facie obvious to one of skill in the art at the time the invention was made to have the administration of the antibiotic delayed by at least one day after administration of said one or more bacteriophage preparation because limitations such as administration and when to administer an antibiotic are being viewed as limitations of optimizing experimental parameters. One would have had a reasonable expectation, barring evidence to the contrary, that the method would be effective for treating a bacterial infection comprising *Pseudomonas aeruginosa*.

***Conclusion***

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
12/18/09

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645